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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED

JUL 27 2007

GROUP 1600

Application Number: 09/657,722
Filing Date: September 08, 2000
Appellant(s): SRIVASTAVA, PRAMOD K.

Adrian M. Antler
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/6/2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US Patent 5,210,076 Berliner et al

Noessner E. *et al "Tumor-Derived Heat Shock Protein 70 Peptide Complexes are Cross-Presented by Human Dendritic Cells."* J. Immunol., vol.169, No.10, (Nov 15, 2002), pp. 5424-32.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. *Claim Rejections - 35 USC § 112, 1st paragraph*

Claims 19,22-31, and 52-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors), at the time the application was filed, had possession of the claimed invention. The written description in this case has not set forth peptides recovered or isolated from the separation of stress protein-peptide complexes derived from tumors, and therefore the written description is not commensurate in scope with the claims which read on peptides in general isolated from tumors.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she) invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

The claims of the instant inventions are drawn to peptide compositions derived from the separation of a stress protein and its associated peptide. Although the stress-protein-peptide complex can be determined and isolated, the claims as currently recited

read on any protein fragment or polypeptide fragment that are derived from a tumor cell from which the complex was initially extracted. One of skill in the art would not be able to determine with any certainty what the composition comprises because the polypeptide and or peptides themselves have not been adequately described. There is a lack of characterization of the peptide or peptides, which makes up the composition, wherein detailed information regarding the structure or amino acid sequence of the peptide or peptides has not been provided in the specification. Furthermore, because the specification has not described the structure and makeup of the peptides in the composition, it can be equivalent to any known composition wherein the composition comprises a peptide or protein fragment.

B. *Claim Rejections - 35 USC § 102*

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Berliner *et al* (US Patent 5,210,076). The claim is drawn to a composition comprising a recovered population of peptides admixed with a pharmaceutically acceptable non-toxic carrier. Berliner *et al* disclose a tyrosinase protein wherein the said protein is found in a compound comprising a pharmaceutically acceptable carrier. As evidenced by Noessner *et al* (J. Immunology 2002,169:5424-5432) tyrosinase is a peptide which can be associated with a HSP70 protein thereby forming a complex. Therefore, because the claims are drawn to a product by process, and because the product being produced are already known, the process by which the product is made does not carry any patentable weight. *In re Thorpe,* 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

(10) Response to Argument

A. *Claim Rejections - 35 USC § 112, 1st paragraph*

Beginning at page 3, appellant summarizes the rejections made of record dated August 20, 2003, wherein the basis for the rejection is a lack of a distinguishing characteristics required in the Revised Interim Written Description Guidelines Training Materials. Appellant indicates that the examiner alleges that only a general structure of the HSP-peptide complex is provided in the instant specification and fails to provide distinguishing characteristics to meet the requirements outlined in the Revised Interim Written Description Guidelines Training Materials. Appellant further summarizes the Office Action of August 20, 2003 indicating that the examiner alleges that there are many possible peptides that can be associated with the HSP-complex of which the specification has not defined and concludes that the skilled artisan cannot readily determine the contents of the claimed peptide composition, the structure of the composition, or any distinguishing characteristics associated with the composition. Appellant at the top of page 4 contends that the written description rejection of record is erroneous because the requirements under 35 USC 112, 1st paragraph for written description only requires that the claimed invention be described in sufficient detail such that one of skill in the art can reasonable conclude that at the time of filing that the inventor had possession of the claimed invention. Appellant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The specification as filed fails to provide one of skill in the art with any indication that the appellant was in possession of the full scope of the claims because one of skill in the art

cannot adequately determine the components of the composition isolated from an HSP-peptide complex. Aside from the fact that the composition comprises peptides, the skilled artisan cannot determine from the disclosure what types of peptides are isolated from the HSP-peptide complex or its amino acid sequence. Moreover, the specification fails to characterize any of the peptides isolated from the HSP-peptide complex or provide any structural-functional relationship of the peptides or provide any common core structure to indicate to one of skill in the art that appellant was in possession at the time of filing. Therefore, one of skill in the art would conclude that at the time of filing, the applicant was not in possession of the invention as claimed, because they cannot adequately determine the components of the composition.

Beginning on page 4, second paragraph, appellant contends that the written description rejection of record is misplaced because the claims are drawn to a product-by-process. Appellant cites *In re Luck*, *Ex parte Pantzer and Feier, In re Thorpe,* and *Atlantic Thermoplastics Co., Inc v. Faytex Corp.,* to support assertions that when a product cannot be described through a direct means, a composition can be described in terms of its method of preparation. Beginning on page 5, appellant further supports their assertions that a product can be claimed by a means of a process, and that in fact the instantly claimed invention is a product-by-process claim. Appellant's arguments have been carefully considered but are not deemed persuasive to overcome the rejections of record. Because the population of the peptides recovered during each round of purification would be different and distinct, and because the tumor cells from which the population of peptides have not been disclosed, one of skill in the art would

not be able to determine which of the thousand if not millions of peptides extracted from the claimed process are recovered. Further, the structure of such peptides cannot be adequately determined or defined because peptides derived from said tumors would be peptide fragments of unknown length and sequences. MPEP 2113, states that "if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, the whole or partial structure of the peptide recovered using the claimed method cannot be determined, because no identifying characteristics have been taught and one of skill in the art would not be able to determine whether the recovered product is already within the public domain. Applicant's reliance on *In re Luck* is misplaced, because the method must define a structure in whole or in part, of which neither is the case in the instant invention. No identifiable characteristics or identifiable means of determining the structure have been set forth. Therefore, because the exact nature or structure of the peptide claimed cannot be determined by the skilled artisan, and because the process by which the product claimed does not define a definitive population of peptides either in whole or in part, one of skill in the art would not be able to determine that the applicant was in possession of the invention at the time the invention was made.

Finally beginning on page 5, last paragraph, applicant summarizes the goal of the instant invention as a means to capture the distinct antigenic profile of a given tumor for use in immunotherapy and further indicates that the instant invention circumvents

the need to identify individual antigens associated with the HSP moleculeand doing so would be an impractical task. Appellant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The fact that something is difficult or daunting is not sufficient in itself to not describe what the appellant is intending to claim. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. see *In re Gardner et al.* 166 USPQ 138 (CCPA 1970).

Therefore, for reasons set forth above, Appellants arguments have been fully and carefully considered, but are not considered sufficient to rebut the *prima facie* case of lack of written description and it is believed that the rejections should be sustained.

B. Claim Rejections - 35 USC § 102

Beginning on page 6, appellant summarizes the rejection of record dated March 8, 2004 and concludes by indicating that the cited reference of Berliner *et al* (US Patent 5,210,076 – herein `076) as evidenced by Noessner *et al* does not render claim 19 anticipated. Beginning at page 6, last paragraph appellant summarizes the invention of Berliner *et al*, indicating that the `076 patent teaches the use of melanin, its variants, analogs and derivatives and other substances including tyrosinase, for the purposes of increasing melanin in tissue with neurodegenerative diseases. Appellant further indicates that the role of tyrosinase as an enzyme involved in the synthesis of melanin and it derivatives and further contends that the `076 patent does not disclose or suggest

the isolation of a population of peptides noncovalently associated with stress proteins in mammalian tumor cells. Appellant then asserts that the rejection is erroneous because the Berliner *et al* reference fails to teach each and every limitation of the claimed invention, specifically, the reference does not teach a population of peptides that are recovered from noncovalently complexed proteins. Appellant indicates that the instantly claimed invention is drawn to a population of heterogenous mixture of peptides. Appellant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The claims of the invention are drawn to a composition of peptides with a pharmaceutical composition. MPEP 2113 [R-1] states, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966* (Fed. Cir. 1985). Moreover, MPEP also states "[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223* (CCPA 1979). In the instant case, the prior art teaches a peptide, tyrosinase, that is capable of

binding to HSP in a noncovalent fashion (see evidence of Noessner *et al*). The specification has not provided any indication that the method of producing the population of peptides imparts any structurally distinct aspect. Moreover, the peptides in this case can be defined because the identity of the peptide has a specific amino acid sequence. Therefore, because the product is taught in the prior art and can be defined by a specific sequence, and because the specification fails to teach any specific structural distinction between the prior art peptides and those claimed, the claims are anticipated.

In addition, the claims do not specifically limit the peptide population to heterogeneous populations and therefore the peptide taught by Berliner *et al* falls within the scope of peptide population claimed. The Noessner *et al* reference was provided only to indicate that tyrosinases are able to bind to HSP in noncovalent form and therefore potential a peptide that is found in the population claimed.

Therefore, for reasons set forth above, Appellants arguments and exhibits have been fully and carefully considered, but are not considered sufficient to rebut the prima facie case of lack of utility and it is believed that the rejections should be sustained.

For the above reasons, it is believed that the rejections should be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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/Christopher Yaen/
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July 23, 2007

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